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## **I. SUMMARY OF ARGUMENT**

From February 1, 2006, through December 31, 2011, the Defendants violated the False Claims Act by submitting to Medicare 14,329 claims under CPT Code 92120 for single eye pressure (IOP) measurements taken with a Tono-Pen. The Ton-Pen cannot measure directly or indirectly facility of outflow (C) and therefore cannot meet the plain meaning of CPT Code 92120. Thus, the Defendants' 14,329 Medicare claims were false.

The Defendants contracted with outside billing companies to process their 14,329 Medicare claims and in doing so, caused these billing companies to present false claims with the Medicare program.

The Defendants established a procedure to bill Medicare under CPT Code 92120 for every measurement of eye pressure (IOP) with a Tono-Pen. The Defendants established and perpetuated this procedure with deliberate ignorance in the absence of guidance or approval from the Centers for Medicare and Medicaid Services (CMS). The Defendants' interpretation of CPT Code 92120 was patently unreasonable, implausible, and plainly lacking in merit.

As a result, the Defendants knowingly presented or caused to be presented 14,329 false claims to the United States that caused the Medicare program to pay the Defendants \$798,853.77 erroneously. The United States is entitled to receive treble damages and civil penalties.

## **II. BACKGROUND**

### **A. The Medicare Program**

In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program, to pay for the costs of health care services for certain individuals. HHS is responsible for the administration and supervision of the Medicare program,

which it does through CMS, an agency of HHS. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease.<sup>1</sup> (Ex. A, ¶¶ 2, 8.) *See* 42 U.S.C. §§ 426, 426-1. The Medicare program consists of four parts: A, B, C, and D. Part A of the Medicare Program authorizes payment for institutional care, including hospital, skilled nursing facility and home health care. (Ex. A, ¶ 3.) *See* 42 U.S.C. §§ 1395c-1395i-4. Part B of the Medicare program authorizes payment for home health care, physician services, and other health services. (Ex. A, ¶ 5.) *See* 42 U.S.C. § 1395k. Under Part B, Medicare will generally pay 80 percent of the “reasonable” charge for medically necessary items and services provided to beneficiaries. *See* 42 U.S.C. §§ 1395l (a)(1), 1395y(a)(1). For most services, the reasonable charge has been defined as the lowest of (a) the actual billed charge, (b) the provider’s customary charge, or (c) the prevailing charge for the service in the locality. (Ex. A, ¶ 21.) *See* 42 C.F.R. §§ 405.502-504.

To assist in the administration of Medicare Part B, CMS contracted with carriers. Carriers, typically insurance companies, were responsible for processing and paying Part B claims. (Ex. A, ¶ 10.) Beginning in November 2006, Medicare Administrative Contractors (“MACs”) began replacing both the fiscal intermediaries and carriers. The MACs generally act on behalf of CMS to process and pay Part A and Part B claims and perform administrative functions on a regional level. (Ex. A, ¶ 11.) In Texas, Trailblazer Health Enterprises, LLC (“Trailblazer”) served as the fiscal intermediary and carrier until August 2007, at which time it was awarded a contract to serve as the MAC for the multi-state region Jurisdiction 4 which includes Texas. In November 2012, Novitas Solutions, Inc. (“Novitas”) succeeded Trailblazer as the MAC for Jurisdiction H. (Ex. A, ¶ 13.)

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<sup>1</sup> Mrs. Ruth Ledbetter’s affidavit is attached as Exhibit “A.”

Physicians, non-physician practitioners, and other health care suppliers must enroll in the Medicare program to be eligible to receive Medicare payment for covered services including ophthalmological services provided to Medicare beneficiaries. (Ex. A, ¶ 14.) In order for providers or suppliers to participate in and receive payment from the Medicare Program, they must meet the eligibility requirements for program participation. For some providers, this includes a certification of compliance with the conditions of participation, or standards, set forth in Federal regulations. (Ex. A, ¶ 15.) The National Provider Identifier (“NPI”) is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare. (Ex. A, ¶ 16.) Once a Medicare provider renders a service(s), he/she will bill for the service(s) to the appropriate Medicare A/B contractor. (Ex. A, ¶ 17.) The Administrative Simplification Compliance Act (ASCA) requires that Medicare claims be sent electronically unless certain exceptions are met (The exceptions are noted in CMS IOM Publication 100-04, Chapter 24, and Sections 90.2 and 90.3). (Ex. A, ¶ 18.) Each request for payment or bill submitted for an item or service payable under Medicare Part B must include the name and unique physician identification number for the referring physician. (Ex. A, ¶ 19.) The provider is paid by electronic funds transfer (EFT). (Ex. A, ¶ 20.)

#### **B. Ophthalmological Services Under Medicare**

Medicare covers and reimburses ophthalmological services including the evaluation and management of glaucoma. Ophthalmological services are divided into three categories: (1) intermediate ophthalmological services, (2) comprehensive ophthalmological services, and (3) special ophthalmological services. (Ex. A, ¶ 22.)

Intermediate services consists of an evaluation of a new or existing condition complicated with a new diagnostic or management problem not necessarily related to the primary diagnosis. The intermediate service includes a history, general medical observation, external ocular and adnexal examination and other diagnostic procedures, including tonometry, as indicated. On a claim for reimbursement, the provider or supplier will use the CPT Code 92002 for new patients or CPT Code 92012 for established patients.<sup>2</sup> (Ex. A, ¶ 23; Ex B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.) As an intermediate service, a home visit for the evaluation and management of a new patient, requires 3 key components: a comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Physicians typically spend 60 minutes face-to-face with the patient and/or family. A home visit for the evaluation and management of an established patient, requires at least 2 of these 3 key components: an expanded problem focused interval history; an expanded problem focused examination; medical decision making of low complexity. Physicians typically spend 25 minutes face-to-face with the patient and/or family. On a claim for reimbursement, the provider or supplier will use the CPT Code 99344 for new patients or CPT Code 99348 for established patients. (Ex. A, ¶ 24; Ex. B, pp. 3-6, 13-15, 22-23, 30-32, 39-40. )

Comprehensive services consist of a general evaluation of the complete visual system with the initiation of diagnostic and treatment programs. The comprehensive service includes a history, general medical observation, external and ophthalmoscopic examinations, gross visual fields and basic sensorimotor examination, and often includes as indicated: biomicroscopy, examination with cycloplegia or mydriasis and tonometry. On a claim for reimbursement, the

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<sup>2</sup> Excerpts from the American Medical Association's Current Procedural Terminology (CPT) Manual for years 2007 – 2011 are attached as Exhibit "B."

provider or supplier will use the CPT Code 92004 for new patients or CPT Code 92014 for established patients. (Ex. A, ¶ 25; Ex. B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.) As a comprehensive service, a home visit for the evaluation and management of an established patient, requires at least 2 of these 3 key components: a detailed interval history; a detailed examination; medical decision making of moderate complexity. Physicians typically spend 40 minutes face-to-face with the patient and/or family. On a claim for reimbursement, the provider or supplier will use the CPT Code 99349 for established patients. (Ex. A, ¶ 26; Ex. B, pp. 3-6, 13-15, 22-23, 30-32, 39-40.)

For billing purposes, intermediate and comprehensive services constitute integrated services in which medical decision making cannot be separated from the examining techniques used. Itemization and billing separately for service components, such as tonometry, is not allowed. (Ex. A, ¶ 27; Ex. B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.) Special services, such as tonography, are services in which a special evaluation of part of the visual system is made, which goes beyond the services included under intermediate or comprehensive services, or in which special treatment is given. Special services may be billed in addition to intermediate or comprehensive services. (Ex. A, ¶ 28; Ex. B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.) As a special ophthalmological service, tonography could be billed under CPT Code 92120. As of January 1, 2012, tonography is no longer a covered service under Medicare or the American Medical Association's Current Procedural Terminology codebook. (Ex. A, ¶ 29; Ex. B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.) CPT Code 92120 states "Tonography with interpretation and report, recording indentation tonometer method or perilimbal suction method." This procedure code only covers the procedure tonography and provides for only two methods to perform the

procedure tonography, recording indentation tonometer method or perilimbal suction method.

(Ex. A, ¶ 30; Ex. B, pp. 7-10, 16-19, 24-27, 33-36, 41-45.)

### **C. Tonography**

Aqueous humor is a dynamic intraocular fluid that is vital to the health of the eye.

Aqueous humor maintains the optical properties of the eye by stabilizing the ocular structure and nourishing the avascular lens and cornea.<sup>3</sup> (Ex. C, p. 15; Ex. D, p. 24.) Aqueous humor is a relatively cell-free, protein free fluid that is formed or produced by the ciliary body.<sup>4</sup> (Ex. J, pp. 29-32, 129-132, 231-234, 333-336, 433-436.) The aqueous humor enters the posterior chamber, flows around the lens, and passes between the iris and the lens.<sup>5</sup> (Ex. E, p. 20; Ex. F, p. 17; Ex. J, pp. 29-32, 129-132, 231-234, 333-336, 433-436.) The aqueous humor then enters the anterior chamber through the pupil and exits the eye at the anterior chamber. (Ex. C, p. 15; Ex. E, p. 20; Ex. F, p. 17; Ex. J, pp. 29-32, 129-132, 231-234, 333-336, 433-436.) The circulating aqueous humor serves several purposes or functions. It helps maintain eye pressure or intraocular pressure (IOP) at a level that will preserve the normal ocular structure and function. In place of a vascular system, it supports the avascular structures of the eye, including the cornea, lens, and trabecular meshwork. (Ex. C, p. 17; Ex. D, p. 29; Ex. E, p. 20.) It provides the eye with essential nutrients including oxygen, glucose, and amino acids. It removes metabolites and toxic substances such as lactic acid and carbon dioxide. (Id.)

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<sup>3</sup> Excerpts from *Shields' Textbook of Glaucoma Fifth Edition* are attached as Exhibit "C;" Excerpts from *Glaucoma Science and Practice* are attached as Exhibit "D."

<sup>4</sup> Excerpts from the American Academy of Ophthalmology's *Basic and Clinical Science Courses* for 2007-2008, 2008-2009, 2009-2010, 2010-2011, and 2011-2012 are attached as Exhibit "J;" This exhibit will be filed under seal as it is designated as confidential with access restricted per court order issued July 6, 2016.

<sup>5</sup> Excerpts from *Becker-Shaffer's Diagnosis and Therapy of the Glaucomas Seventh Edition* are attached as Exhibit "E;" Excerpts from *Chandler and Grant's Glaucoma Fifth Edition* are attached as Exhibit "F."

Aqueous humor flows constantly through the anterior segment of the eye that enters the venous system via trabecular meshwork and Schlemm's canal. This pathway or fluid movement is referred to as conventional outflow or aqueous humor outflow. (Ex. C, p. 43; Ex. E, p. 19; Ex. J, pp. 32-34, 132-134, 234-236, 336-338, 436-438.) Primarily, the resistance to aqueous humor outflow or balance between aqueous humor production and outflow determines eye pressure or IOP. An increase or elevation in eye pressure results in reduced or resistance to aqueous outflow. (Ex. D, pp. 34, 38; Ex. E, p. 66; Ex. J, pp. 32-34, 132-134, 234-236, 336-338, 436-438.) The facility of outflow or outflow facility is a measurement of the ease with which aqueous humor leaves the eye by conventional outflow. Outflow facility represents the rate at which fluid leaves the eye by pressure. A lower or decrease in facility of outflow results in an increase in or elevated eye pressure. (Ex. C, p. 43; Ex. D, p. 75; Ex. J, pp. 32-34, 132-134, 234-236, 336-338, 436-438.) The regulation of eye pressure (IOP) depends on (a) production of aqueous humor, (b) resistance to aqueous humor outflow, and (c) episcleral venous pressure. Eye pressure (IOP) is a function of the rate at which aqueous humor enters the eye (inflow) and the rate at which it leaves the eye (outflow). When inflow equals outflow, a steady state exists, and the pressure remains constant. (Ex. C, pp. 8-11.)

Glaucoma, the second most common cause of permanent blindness in the U.S., is due to progressive optic nerve damage in the eye related to elevated eye pressure (IOP).<sup>6</sup> (Ex. G, p. 5; Ex. H, 8:15-15:9; Ex. J, pp. 15-17, 115-116, 217-218, 319-320, 419-420.) The only treatment to stop or slow the progression of vision loss and optic nerve damage is lowering the eye pressure with medications, laser, or surgery. There is currently no treatment to recover lost vision or optic

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<sup>6</sup> A copy of David A. Lee, M.D.'s report is attached as Exhibit "G." His report with exhibits can be found at Docket Nos. 72, 72-1 to 72-16; A copy of David A. Lee, M.D.'s deposition transcript is attached as Exhibit "H."

nerve damage or blindness from glaucoma. (Ex. G, p. 5; Ex. H, 8:15-15:9.) Eye pressure (IOP) that is too high for continued health of the nerve is universally accepted as one of the most important risk factors to developing glaucoma. Aqueous formation (F), facility of outflow (C), and episcleral venous pressure ( $P_v$ ) are the major intraocular determinants of eye pressure (IOP). (Ex. E, p. 20.) Eye pressure (IOP) can be measured with the Goldmann equation:  $P_o = F/C + P_v$ . In the equation,  $P_o$  represents the eye pressure (IOP) in the undisturbed eye in mm Hg. The aqueous formation (F) is in  $\mu\text{l}/\text{min}$ , the facility of outflow (C) is in  $\mu\text{l}/\text{min}/\text{mm Hg}$ , and the episcleral venous pressure ( $P_v$ ) is in mm Hg. Eye pressure ( $P_o$ ) increases when either aqueous formation (F) increases, episcleral venous pressure ( $P_v$ ) increases, or the outflow facility (C) decreases. (Id.) Tonography is a clinical test and most widely used to estimate or measure the facility of outflow (C) or the ease or lack of ease, with which aqueous humor leaves the eye.<sup>7</sup> (Ex. C, p. 54; Ex. D, p. 75; Ex. E, p. 65; Ex. G, p. 8; Ex. H, 120:25-121:20, 124:19-22, 129:16-21, 181:9-182:22; Ex. I, p. 8; Ex. J, pp. 34, 134-136, 236-238, 338-340, 438-440.)

Tonography offers the ophthalmologist another tool for the better evaluation and treatment of the glaucoma patient. (Ex. I, p. 8.) Tonography was usually performed, calculated, and interpreted by ophthalmologists or specially-trained ophthalmic technicians. (Ex. G, p. 9.) Clinically, the principal reason for resorting to tonography is that tonometry, the measurement of eye pressure (IOP), alone may not give enough information about the eye unless repeated several times in a course of 24 hours. Tonometry may find the eye pressure (IOP) to be normal during some portions of the day while the facility of aqueous outflow is simultaneously abnormal. (Ex. F, p. 46.) Tonography has been used as an adjunct in diagnosing glaucoma because abnormally

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<sup>7</sup> Excerpts from *Tonography and the Glaucomas* are attached as Exhibit "I."

low facility of outflow (C) was thought to predict the development of nerve damage in patients with elevated eye pressure (IOP), or thought to correlate with wide diurnal fluctuation in eye pressure (IOP). (Ex. G, p. 9.) Tonography has provided valuable information about the pathophysiology of glaucoma and the mechanism of action of various treatment modalities. (Ex. C, p. 54; Ex. D, p. 75; Ex. E, pp. 65-66.) The current use of tonography is now limited to the research setting to investigate the outflow mechanisms in the eye after various pharmacologic, laser, and surgical treatments for glaucoma. The clinical use of tonography to diagnose and manage patients with glaucoma or glaucoma suspects ceased in the 1980's because of its unreliability and the only company manufacturing this device, V. Mueller, went out of business. (Ex. D, p. 75; Ex. G, p. 9; Ex. H, 181:9-182:22; Ex. J, pp. 34, 134-136, 236-238, 338-340, 438-440.)

Tonography, in ophthalmology, means recording eye pressure (IOP) during several minutes while the eye is subjected to the weight of the electronic Schiotz tonometer, the purpose being to determine how rapidly the pressure drops under this load, and from this to calculate the facility of aqueous outflow. (Ex. F, p. 46; Ex. J, pp. 34, 134-136, 236-238, 338-340, 438-440.) Tonography is a means of estimating the facility of outflow (C) by raising the eye pressure (IOP) with the weight of an indentation tonometer and observing the subsequent delay curve in the eye pressure (IOP) that is continuously measured over time. The weight of the tonometer plunger (usually 5 g or 10 g) on the cornea raises the eye pressure (IOP) from the baseline ( $P_o$ ) to a new higher level ( $P_t$ ). (Ex. G, pp. 8-9; Ex. J, pp. 34, 134-136, 236-238, 338-340, 438-440.) The elevated eye pressure (IOP) causes an increased rate of aqueous outflow, leading to a change in the aqueous volume (V). The rate of volume decrease ( $\delta V/T$ ) equals the rate of outflow. (Id.)

The standard tonographic technique is to measure the eye pressure (IOP) continuously for 4 minutes ( $T=4$ ). The change in eye pressure (IOP) during this time is computed as an arithmetic average of pressure increments for successive half-minute intervals ( $\text{Ave. } P_t - P_o$ ). The facility of outflow (C) is then derived from Grant's equation:  $C = V/T (\text{Ave. } P_t - P_o)$ . (Id.)

The equipment needed for tonography consists of an electronic Schiotz tonometer and a recorder to make a record of the movement of the plunger of the tonometer. When an electronic Schiotz tonometer is not available, use can be made of a pneumotonometer; the procedure can then be called pneumotonography. (Id.) With the recorder running, the electronic Schiotz tonometer is calibrated at scale readings of 0 and 7. The recording needle is then set at 0 for the subsequent readings. The patient is in a supine position, fixing their eye on a target overhead. (Ex. E, p. 67; Ex. F, pp. 46-47; Ex. G, p. 9; Ex. H, 114:4-120:16, 126:16-128:10.) After instilling a topical anesthetic on the cornea, the baseline eye pressure (IOP) is measured with a Perkins applanation tonometer to measure  $P_o$ . (Ex. G, p. 9.) Then the electronic indentation tonometer tip is gently placed on the cornea and held steady in this position until a smooth tracing has been obtained for a full 4 minutes. A good tracing will have fine oscillations and a gentle downward slope. (Ex. D, pp. 75-76; Ex. E, p. 67; Ex. F, pp. 46-47; Ex. G, p. 9; Ex. H, 114:4-120:16, 126:16-128:10.) The slope of the tracing is then estimated by placing a freehand line through the middle of the oscillations. The scale readings are noted at the beginning and end of the 4-minute tracing.  $P_o$  and the change in scale readings over 4 minutes (R) are then used to obtain the facility of outflow (C) from special tonographic tables. (Id.)

Interpreting tonographic results has many potential errors due to high variability. Normal facility of outflow (C) is  $0.28 \mu\text{l/min/mmHg}$ , and eyes with glaucoma have values less than 0.18

$\mu\text{l}/\text{min}/\text{mmHg}$ . The P<sub>o</sub>/C Ratio is 56 in normal eyes, but is greater than 100 in eyes with glaucoma. There is controversy regarding the value of tonography in the diagnosis and management of glaucoma. (Ex. C, pp. 54-56; Ex. E, pp. 67-69; Ex. F, pp. 46-47; Ex. G, p. 9.) The perilimbal suction cup is an alternate method of measuring the facility of aqueous outflow. The perilimbal suction cup is merely a substitute and adjunct method of studying the resistance to the flow of aqueous out of the eye. (Ex. C, p. 55; Ex. I, pp. 358-374.) The device is applied to the sclera with a vacuum 50 mm Hg below atmospheric pressure. The vacuum occludes intrascleral and episcleral venous drainage and raises eye pressure (IOP). (Id.) The facility of outflow is calculated from the decline in eye pressure (IOP) after the suction cup is removed. The suction cup technique usually gives lower values for outflow facility than does tonography. (Id.)

#### **D. Tonometry**

Eye pressure (IOP) is a very important risk factor for the development of glaucomatous optic nerve damage. Although other risk factors affect an individual's susceptibility to glaucomatous damage, eye pressure (IOP) is the only one that can be altered at this time. (Ex. J, pp. 35-41, 136-142, 238-244, 340-346, 440-446.) In a clinical setting, tonometers measure eye pressure (IOP) with a force that indents or flattens the eye. (Id.) Currently, tonometers are generally divided into two major groups, referred to as applanation and indentation instruments. (Ex. C, p. 65.) Applanation tonometry is the most common method of measuring eye pressure (IOP). This method is based on the Imbert-Fick principle which states that the pressure inside an ideal dry thin-walled sphere equals the force necessary to flatten its surface divided by the area of the flattening. (Ex. J, pp. 35-41, 136-142, 238-244, 340-346, 440-446.) The eye pressure (P)

equals force (F) divided by area (A) or  $P = F/A$ . (Id.) In applanation tonometry, the cornea is flattened, and the eye pressure (IOP) is determined by measuring the applanating force and the area flattened. (Id.) The Goldmann applanation tonometer measures the force necessary to flatten an area of the cornea of 3.06 mm diameter. The resistance of the cornea to flattening is counterbalanced by the capillary attraction of the tear film meniscus for the tonometer head. The eye pressure (IOP), in mm Hg, equals the flattening force, in grams, multiplied by 10. (Id.) Ophthalmologists and optometrists can measure eye pressure (IOP) in patients seated at a slit lamp with the Goldmann tonometer.<sup>8</sup> (Ex. G, p. 7; Ex. H, 48:21-51:23, 54:16-18, 56:2-58:17; Ex. M, pp. 29-32.)

The Goldmann tonometer is mounted on a slit-lamp in such a way that the examiner's view is directed through the center of a plastic biprism, which is used to touch an anesthetized cornea. With the cornea and biprism illuminated by a cobalt blue light from the slit-lamp, the biprism is brought into gentle contact with the apex center of the cornea. (Ex. C, pp. 42-44; Ex. E, pp. 65-68; Ex. G, p.7.) The fluorescence of the stained tears facilitates visualization of the tear meniscus at the margin of the contact between cornea and biprism. The fluorescent semi-circles are viewed through the biprism, and the force against the cornea is adjusted until the inner edges overlap. (Id.) The prisms are adjusted so that the inner margins of the semi-circles just overlap when 3.06 mm of cornea is applanated. The biprism is attached by a rod to a housing, which contains a coil spring and series of levers that are used to adjust the force of the biprism against the cornea. (Id.) By suitable adjustment of the graduated drum, varying the force applied to the cornea, the arcs should then be seen in sharp focus, equal in size and the arcs can be made to

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<sup>8</sup> David A. Wallace, M.D.'s affidavit is attached as Exhibit "M."

overlap so that the inner edge of the upper arc can be aligned with the inner edge of the lower arc. (Id.) The numerical reading on the drum indicates grams of force applied by the tonometer and provides the eye pressure (IOP) measurement in mm Hg. (Id.) Applanation measurements are safe, easy to perform, and relatively accurate in most clinical situations. The Goldmann applanation tonometer is the most valid and reliable. (Ex. J, pp. 35-41, 136-142, 238-244, 340-346, 440-446.)

In 1962, Ralph Mackay and Elwin Marg patented and introduced the Mackay-Marg tonometer to measure eye pressure (IOP).<sup>9</sup> (Ex. N, pp. 15-23.) The tonometer consists of a movable plunger, 1.5 mm in diameter, which protrudes slightly from a surrounding footplate or sleeve. The movements of the plunger are measured by a transducer and recorded on a paper strip. (Ex. C, p. 45; Ex. E, p. 69-70; Ex. J, pp. 35-41, 136-142, 238-244, 340-346, 440-446; Ex. N, pp. 15-23.) To measure eye pressure (IOP), the instrument's tip momentarily touches the cornea for about one second. (Id.) No indentation of the eyeball is necessary and the pressure measurement is obtained during a fast but light and gentle contact with the eyeball, which momentarily flattens a portion of the surface. (Ex. M, pp. 33-35; Ex. N, pp. 15-23.) As the instrument's tip touches the cornea, the tracing on the paper, which represents the force required to peep the plate flush with the sleeve, rises until the applanated or flattened area on the cornea reaches a diameter of 1.5 mm. (Ex. C, p. 45; Ex. M, pp. 33-35.) At the tracing's crest, the pressure against the plate represents the eye pressure (IOP) and the force required to bend the cornea. (Id.) From the crest, the tracing then falls as the effect of the corneal bending pressure is transferred to the footplate and a notch is seen on the pressure tracing. (Ex. C, p. 45; Ex. E, p.

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<sup>9</sup> Certified copies of U.S. Patent No. 4,747,296 and U.S. Patent No. 3,049,001 are attached as Exhibit "N."

69-70; Ex. M, pp. 33-35.) When the flattened area of the cornea reaches a diameter of 3.0 mm, the height of the notch is the measure of eye pressure (IOP) in mm Hg. (Id.) Because this tonometer records the eye pressure (IOP) instantaneously, several readings should be averaged to reduce the effects of the cardiac and respiratory cycles. (Ex. C, p. 45; Ex. E, p. 69-70.)

In 1988, a group that included David M. Wallace, M.D. patented and introduced a miniaturized, digital version of the Mackay-Marg tonometer called the Tono-Pen. (Ex. M, Aff. Wallace ¶¶ 2-5, pp. 11-23, 35-40; Ex. N, pp. 1-14.) Like the Mackay-Marg tonometer, the Tono-Pen only measures eye pressure (IOP). Unlike the electronic Schiotz tonometer, the Tono-Pen does not measure, directly or indirectly, facility of outflow (C).<sup>10</sup> (Ex. K, pp. 1-7, 44-50, 68-74, 96-102, 124-130, 158-163, 165-171, 197-203, 229-235, 264-267, 277-285; Ex. L, Aff. Taylor ¶¶ 7-11, pp. 1-10, 44-50, 68-74, 96-102, 124-130, 152-158, 184-190, 216-222; Ex. M, Aff. Wallace ¶¶ 2-5, pp. 11-23, 25, 35-40; Ex. N, pp. 1-14.) The Tono-Pen is a battery powered, hand-held self-contained electronic tonometer with a digital readout for displaying pressure in millimeters of mercury (mm Hg). The tonometer includes a transducer which is a solid state pressure sensitive element and which produces a voltage proportional to eye pressure (IOP). (Ex. M, Aff. Wallace ¶¶ 2-5, pp. 11-23, 25, 35-40; Ex. N, pp. 1-14.) An electrical waveform is produced by gently bringing the transducer in contact with the cornea. The waveform is converted to a digital signal and processed by a single chip microprocessor. (Id.) Once a carrier or reference signal is removed or nullified, the microprocessor software detects the baseline condition, looks for a series of valid measurements (4-10), and calculates the average eye pressure (IOP) along with an estimate of reliability. The average eye pressure (IOP) value and the reliability indicator are

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<sup>10</sup> Business records for Reichert Technologies, Inc., manufacturer of the Tono-Pen, are attached as Exhibit “K;” David Alan Taylor’s affidavit is attached as Exhibit “L.”

displayed on a liquid crystal display. (Ex. G, pp. 7-8; Ex. H, 91:13-98:21, 145:14-146:24, 194:13-17; Ex. K, pp. 19-25, 56-59, 80-83, 108-111, 136-139, 181-183, 213-215, 245-247; Ex. M, Aff. Wallace ¶¶ 2-5, pp. 11-23, 25, 35-40; Ex. N, pp. 1-14.) In seconds, the Tono-Pen measures eye pressure (IOP) at a single point in time. The Tono-Pen cannot measure eye pressure (IOP) continuously over several minutes. (Ex. G, pp. 7-8; Ex. L, Aff. Taylor ¶¶ 7-11; Ex. M, Aff. Wallace ¶¶ 3,5, pp. 35-41.) The Tono-Pen can measure a patient's eye pressure (IOP) in any position including seated, supine, or standing. (Ex. M, Aff. Wallace ¶ 4.)

In indentation tonometry, a known weight is placed on the cornea and the eye pressure (IOP) is estimated by measuring the deformation or indentation of the globe. As the first tonometer developed (1926), the Schiotz tonometer is the prototypical indentation tonometer. (Ex. E, pp. 71-73; Ex. G, p. 7; Ex. H, 74:25-79:3, 83:17-86:3; Ex. J, pp. 41, 142, 244, 346, 446; Ex. M, p. 4; Ex. N, pp. 11, 18.) The Schiotz tonometer measured the actual indentation of the cornea by a plunger which was pressed under a fixed force directly against an anesthetized eyeball while the patient laid supine. (Id.) The Schiotz tonometer consists of a metal plunger that slides through a hole in a concave metal footplate. The plunger supports the hammer device connected to a needle that crosses a scale. (Ex. C, pp. 49-50; Ex. D, pp. 63-64; Ex. E, pp. 71-73.) The plunger, hammer, and needle weigh 5.5 g and can be increased to 7.5, 10, or 15 g with additional weights. The more the plunger indents the cornea, the higher the scale reading and the lower the eye pressure (IOP). (Id.) However, the eye pressure that the Schiotz tonometer measures is actually the eye pressure that results when the tonometer is in contact with the eye which is higher than the patient's eye pressure (IOP). The indentation is read on a linear scale on the instrument and converted to millimeters of mercury by a conversion table to get the patient's

eye pressure (IOP). (Ex. C, pp. 49-50; Ex. D, pp. 63-64; Ex. E, pp. 71-73; Ex. G, p. 6; Ex. J, pp. 41, 142, 244, 346, 446; Ex. M, p.4.) Unlike the electronic Schiotz tonometer, the standard Schiotz tonometer does not measure, directly or indirectly, facility of outflow (C). The standard Schiotz tonometer does not continuously record eye pressure (IOP); it can only provide a single measurement of eye pressure (IOP) at a time. (Ex. E, pp. 73-74; Ex. H, 114:4-120:16; Ex. M, pp. 28-29.) Because of a number of practical and theoretical problems, the Schiotz tonometer is rarely used. (Ex. F, p. 43; Ex. J, pp. 41, 142, 244, 346, 446.)

### **III. STATEMENT OF FACTS**

Mustapha Kibirige, M.D. graduated from the University of New Mexico School of Medicine in 1993 and completed his residency in ophthalmology at Louisiana State University – Shreveport (LSU-S) in 1999.<sup>11</sup> (Ex. O, 9:21-15:20, Dep. Ex. 1.) In 1999, Dr. Kibirige obtained his license to practice medicine in Texas. (Ex. O, 26:1-3, Dep. Ex. 1.) In 2000, Dr. Kibirige joined Physician Eye Associates, an ophthalmology practice located at 2000 Crawford Street, Houston, Texas 77002, and owned by Dr. Hargrove Wooten. Dr. Kibirige practiced as an ophthalmologist under Dr. Wooten until Dr. Wooten passed away six months after Dr. Kibirige joined the practice. (Ex. O, 29:17-33:16.) Upon Dr. Wooten’s death, Dr. Kibirige and Michael Mapp, M.D., another ophthalmologist who practiced at Physician Eye Associates, inherited Dr. Wooten’s ophthalmology practice. Until 2004, Dr. Kibirige and Dr. Mapp together owned and operated Physician Eye Associates. (Ex. O, 29:17-33:16, 33:17-37:7, 64:19-65:21.) In 2004, Dr. Mapp left Physician Eye Associates to form another ophthalmology practice with his spouse. That same year, Dr. Kibirige closed Physician Eye Associates and reopened in the same location

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<sup>11</sup> Excerpts from Mustapha Kibirige’s deposition is attached as Exhibit “O.”

the ophthalmology practice as Outreach Eyecare. (Ex. O, 64:19-65:21, 67:5-68:13.) In August of 2006, Dr. Kibirige registered Outreach Eyecare as the assumed name for Mustapha Kibirige, M.D., P.A., Dr. Kibirige's professional association registered in October of 2002.<sup>12</sup> (Ex. P, pp. 1-8.) In 2002, Dr. Kibirige obtained a Medicare individual identification number and group number for Mustapha Kibirige, M.D., P.A.<sup>13</sup> (Ex. O, 65:22-66:18; Ex. Q, pp. 1-26.)

In 2004, Jennifer Williams began working for Dr. Kibirige as his office manager at Outreach Eyecare. She supervised the medical staff excluding the optometrists and ophthalmologists who Dr. Kibirige supervised.<sup>14</sup> (Ex. O, 75:12-76:16, Ex. R, 36:20-23, 71:2-7, 75:13-77:12, 85:25-87:3, 97:2-3.) In the beginning, Outreach Eyecare consisted solely of Dr. Kibirige and Jennifer Williams. Dr. Kibirige examined and treated patients, completed his own billing sheets, and gave them to a third party billing company. (Ex. O, 70:14-71:13; Ex. R, 37:22-38:8.) By 2006, Dr. Kibirige or Jennifer Williams hired several technicians, optometrists, and office staff to work at Outreach Eyecare. In 2005, Dr. Kibirige hired Michael Philip Sorensen, O.D., a licensed optometrist, to join Outreach Eyecare.<sup>15</sup> (Ex. O, 70:14-71:13, 116:2-11, 120:22-122:7; Ex. R, 40:12-42:19; Ex. S, 53:14-25, 56:14-57:8, 61:5-12, 62:9-12.) The optometrists assigned their benefits to Outreach Eyecare that allowed the clinic to receive reimbursement from third party payors for their services. (Ex. O, 322:13-325:17.) Dr. Sorensen examined and treated patients primarily in the patient's home and less frequently in the Outreach Eyecare clinic. (Ex. S, 58:24-59:24, 71:3-73:16, 93:19-95:16, 106:2-7, 106:25-108:3.) Dr.

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<sup>12</sup> Secretary of State of Texas official records related to Outreach Eyecare are attached as Exhibit "P."

<sup>13</sup> Centers for Medicare and Medicaid Services official records related to Outreach Eyecare are attached as Exhibit "Q.;" a redacted copy will be filed with an unredacted copy filed under seal.

<sup>14</sup> Excerpts from Jennifer Williams' deposition are attached as Exhibit "R."

<sup>15</sup> Excerpts from Michael Philip Sorensen O.D.'s deposition are attached as Exhibit "S."

Sorensen or a technician working with Dr. Sorensen measured the patient's eye pressure (IOP) in the patient's home with a Tono-Pen or he would measure a patient's eye pressure (IOP) in the Outreach Eyecare clinic with a Goldmann tonometer. (Ex. S, 71:3-73:16, 84:7-23.)

Continuing the same services as Physician Eye Associates, Outreach Eyecare provided general ophthalmological services including the evaluation and management of glaucoma or glaucoma suspect patients. With the assistance of technicians, Dr. Kibirige or his optometrists provided these services in the Outreach Eyecare clinic or patient's home. (Ex. O, 38:3-41:7, 49:24-50:25, 73:1- 21, 119:24-120:24, 123:23-125:24, 139:4-140:17; Ex. R, 82:23-83:20, 100:17-19; Ex. S, 64:17-65:10, 73:5-16.) As part of the evaluation and management of glaucoma or glaucoma suspect patients, Dr. Kibirige or his optometrists with the assistance of the technicians measured the patient's eye pressure (IOP). They measured the patient's eye pressure (IOP) with the Goldmann tonometer or Tono-Pen. (Ex. O, 38:3-41:7, 56:1-58:7, 73:1-21, 77:23-79:11, 98:22-99:16, 119:24-120:24, 181:7-181:25; Ex. S, 64:17-65:10, 67:3-25, 82:9-84:23, 89:1-15.) For house calls, they measured the patient's eye pressure (IOP) only with a Tono-Pen. (Ex. O, 77:23-79:1, 98:22-99:1, 127:20-128:4, 181:17-25; Ex. U, 65:11-16, 77:5-16, 102:13-103:4.) Outreach Eyecare did not have nor did Dr. Kibirige or his optometrists use a Schiotz tonometer, electronic Schiotz tonometer, or any other medical device to measure eye pressure (IOP). No one at Outreach Eyecare including Dr. Kibirige or his optometrists performed tonography. (Ex. O, 55:23-58:7, 98:22-99:16, 180:20-181:6, 231:7-23, 250:2-251:1, 252:2-19, 254:5-14.)

In 2010, Dr. Kibirige hired Emelike U. Agomo, M.D. to become medical director for Outreach Eyecare, see patients, and supervise the optometrists.<sup>16</sup> (Ex. O, 278:25-279:22, 285:18-286:22; Ex. R, 82:23-83:20; Ex. U, 27:22-28:3, 28:18-25, 29:6-30:7, 32:8-32:13, 46:23-47:5.) Dr. Agomo graduated from Howard University College of Medicine in 2005 and completed his residency in ophthalmology at the University of Texas Medical Branch in 2009. He is licensed to practice medicine in Texas. (Ex. U, 9:7-10:18, 11:16-12:7, Dep. Ex 1.) At least once a quarter, Dr. Agomo trained and educated the optometrists regarding Glaucoma including evaluation and management. He also provided medical supervision and guidance to the technicians at Outreach Eyecare. (Ex. U, 40:23-42:25, 57:14-58:14, 81:22-82:7, 220:17-221:15.) Dr. Agomo provided ophthalmological services including the evaluation and management of glaucoma or glaucoma suspect patients in the Outreach Eyecare clinic. (Ex. U, 29:14-30:7.) While Dr. Agomo worked at Outreach Eyecare, a Tono-Pen was used exclusively to measure eye pressure (IOP) for glaucoma or glaucoma suspect patients in the Outreach Eyecare clinic or patient's home. The Goldmann tonometer or the Tono-Pen was used to measure eye pressure (IOP) for non-glaucoma or glaucoma suspect patients in the Outreach Eyecare clinic. No other medical device was used to measure eye pressure (IOP). (Ex. U, 65:11-66:20, 68:25-69:7, 77:5-78:5, 102:14-103:4.) Dr. Agomo never performed tonography and knew that no one at Outreach Eyecare performed tonography. (Ex. U, 176:3-11, 178:18-179:4.)

In 2004, Dr. Kibirige opened K & S Consulting, LLC. to provide management, business development, billing and collections, and finance and accounting services for health care entities.

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<sup>16</sup> Excerpts of Emelike U. Agomo, M.D.'s deposition are attached as Exhibit "U."

In the same year, Outreach Eyecare became K & S Consulting's first client.<sup>17</sup> (Ex. O, 104:25-107:11, 109:20-22, 110:6-111:13; Ex. T, 13:15-23, 29:23-33:13, 35:25-36:3; Ex. V, pp. 1-13.) K & S Consulting provided Outreach Eyecare only with billing, collections, and accounting services. (Ex. T, 35:25-36:10, 80:21-81:18, 92:1-5, 126:7-21.) In 2004, Omar Kiggundo graduated from Yale University with a degree in Economics and in 2006, he joined K & S Consulting as a research analyst and chief operating officer; later he became the chief executive officer. He is Dr. Kibirige's nephew. (Ex. T, 13:5-14:3, 26:1-27:15.) After Outreach Eyecare provided services to their patients, Outreach Eyecare's staff would prepare and provide K & S Consulting with Outreach Eyecare's completed billing sheets (super bills). From these billing sheets, K & S Consulting's coders and billers would code and submit Outreach Eyecare's claims to various health insurance plans including Medicare. (Ex. T, 39:2-40:13, 44:8-22, Ex. 9, Ex. 10.) Outreach Eyecare filled out the billing sheets with the CPT Codes for the services provided. K & S Consulting relied upon Outreach Eyecare to provide the procedure codes for the services rendered. (Ex. T, 39:25-41:22; 44:2-22, Ex. 9, Ex. 10.) K & S Consulting never altered the procedure codes submitted by Outreach Eyecare on its billing sheets. (Ex. T, 43:17-21.) In 2006, K & S Consulting modified Outreach Eyecare's existing billing sheet using the same diagnostic codes and CPT Codes. K & S Consulting changed the old billing sheet's formatting, reduced the billing sheets to one page, and improved the appearance all to make it easier to use.<sup>18</sup> (Ex. T, 92:6-93:25, 105:9-110:18, Ex. 5; Ex. W, pp. 1-3.) Among the listed CPT Codes, Outreach Eyecare's billing sheet included CPT Code 92120 listed as "Pressure Check." (Ex. O, 217:14-

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<sup>17</sup> Excerpts of Omar Kiggundo's deposition are attached as Exhibit "T," a redacted copy will be filed with an unredacted copy filed under seal; Secretary of State of Texas official records related to K & S Consulting, LLC are attached as Exhibit "V."

<sup>18</sup> A copy of a blank billing sheet (superbill) for Outreach Eyecare is attached as Exhibit "W."

224:19, 226:24-227:2, Ex. 9; Ex. T, 110:1-18; Ex. W, pp. 1-3.)

In 2008, Dr. Kibirige purchased and acquired Wills Diagnostic Clinic located at 2000 Crawford Street, Houston, Texas 77002, the same building as Outreach Eyecare. As a family medical practice, Wills Diagnostic Clinic offered general medical services; it did not offer ophthalmological services.<sup>19</sup> (Ex. O, 148:6-150:15; Ex. X, pp. 1-12.) Dr. Kibirige renamed the family medical practice to Outreach Diagnostic Clinic, LLP. K & S Consulting managed day-to-day operations at Outreach Diagnostic Clinic. (Ex. O, 150:4-9, 153:23-154:8.) In 2008, Dr. Kibirige obtained a National Provider Identification (NPI) Number and Medicare group number for Outreach Diagnostic Clinic.<sup>20</sup> (Ex. Y, pp. 1-45.) Outreach Diagnostic Clinic did not provide ophthalmological services nor did their physicians or technicians perform any services for Outreach Eyecare. Likewise, Outreach Eyecare's physicians, optometrists, or technicians did not perform any services for Outreach Diagnostic Clinic. (Ex. O, 155:6-156:2; Ex. U, 216:5-217:1.) Outreach Diagnostic Clinic did not have any equipment to perform ophthalmological services. The clinic did not have any Goldmann tonometers or Tono-Pens. (Ex. O, 167:2-13.) In 2012, Dr. Kibirige closed Outreach Diagnostic Clinic and let go the clinic's physicians and staff. (Ex. O, 150:21-151:22, 171:2-9.)

When Dr. Kibirige opened Outreach Diagnostic Clinic in 2008, Outreach Eye Care and Outreach Diagnostic Clinic entered into a contract with Global Healthcare Alliance (GHA) to provide billing and collection services for Outreach Eyecare and Outreach Diagnostic Clinic. Under the contract, GHA performed billing, collections, payment posting, and patient follow-up

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<sup>19</sup> Secretary of State of Texas official records related to K & S Consulting, LLC are attached as Exhibit "X."

<sup>20</sup> Centers for Medicare and Medicaid Services official records related to Outreach Diagnostic Care are attached as Exhibit "Y.;" a redacted copy will be filed with an unredacted copy filed under seal.

services to both clinics.<sup>21</sup> (Ex. T, 36:16-39:1, 48:6-9, 59:18-60:7, 82:16-82:24; Ex. Z, 11:24-12:12, 17:13-18:25, 20:11-22:10; Ex. AA, pp. 1-22.) K & S Consulting continued to provide accounting services to Outreach Eyecare and started to provide accounting services to Outreach Diagnostic Clinic. (Ex. T, 72:6-13, 82:25-83:16.) GHA's services to both clinics did not include coding or auditing services. GHA did not provide a CPT rate list, charge master, or billing sheets to Outreach Eyecare or Outreach Diagnostic Clinic. (Ex. Z, 16:7-17:7, 33:11-14, 42:16-44:13, 57:19-59:25, Ex. 2, Ex. 3, Ex. 8; Ex. AA, pp. 2-22.) As part of its services to both clinics, GHA published and provided a monthly billing report to both clinics that covered charges, payments, adjustments, and aging accounts. (Ex. T, 51:14-52:7, Ex. 11, Ex. 12; Ex. Z, 31:22-33:10; Ex. AA, pp. 1-22.) For each service billed, Outreach Eyecare or Outreach Diagnostic Clinic prepared the billing sheet, sent the claim information including the CPT code for the service provided electronically through a secured site to GHA. Through its electronic billing system, GHA checked each claim sent from either clinic for completeness not accuracy and if complete, submitted the claim electronically to a third party payor like Medicare. (Ex. O, 83:19-25; Ex. T, 61:10-62:18; Ex. Z, 37:5-40:25, 65:5-66:11; Ex. AA, pp. 1-22.) Outreach Eyecare and Outreach Diagnostic Clinic terminated the contract with GHA in September of 2013 for not collecting enough money. (Ex. T, 71:4-14; 135:13-137:10, Ex. 15; Ex. Z, 27:17-28:3, 61:17-24, 63:13-17, Ex. 9.)

Dr. Kibirige met regularly with Jennifer Williams, Omar Kiggundo, and Dr. Agomo to discuss Outreach Eyecare's operations including billing, collections, and other affairs of the clinic. He would regularly receive and review management and billing reports. (Ex. O, 76:5-16,

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<sup>21</sup> Excerpts of Kevin Goertz' deposition are attached as Exhibit "Z;" Excerpts of deposition by written questions to Global Healthcare Alliance, Inc. is attached as Exhibit "AA."

102:1-104:2, 107:22-108:18, 127:8-19, 281:25-282:6, 283:14-286:22; Ex. T, 133:13-19; Ex. U, 60:22-61:10.) He reviewed and approved the Outreach Eyecare's billing sheet forms used in billing for the services performed at Outreach Eyecare. While Medicare allowed claims for CPT Code 92120, Outreach Eyecare's billing sheets included "Pressure Check" as CPT Code 92120. (Ex. O, 47:3-49:23, 75:2-11, 217:14-25, 220:8-25, 223:24-224:5, 224:20-225:13, 226:15-227:13, 333:9-25, Ex. 9.) Outreach Eyecare's office staff understood that CPT Code 92120 was used every time a Tono-Pen measured a patient's eye pressure (IOP).<sup>22</sup> (Ex. BB, 58:19-59:7, 60:6-12, 69:15-20.) After measuring a patient's eye pressure (IOP) with a Tono-Pen, the examining doctor would mark off CPT Code 92120 on the billing sheet. The doctor would review and complete the billing sheet and return the billing sheet to the office staff. (Ex. O, 226:24-229:13, 247:6-9, 344:12-346:17; Ex. R, 79:20-81:18, 91:11-22, 131:2-134:2, 146:13-148:4; Ex. T, 61:10-62:18; Ex. U, 36:3-38:8, 38:15-24, 72:2-15, 156:24-160:17, 188:1-25.) In turn, the office staff sent the billing sheet's information to Outreach Eyecare's billing company to be submitted to a third party payor like Medicare. (Id.) Dr. Agomo completed his own billing sheets, but did not review or check the other doctors' billing sheets nor involve himself in Outreach Eyecare's billing procedures. (Ex. U, 32:8-20, 38:15-19, 56:18-57:1, 81:22-82:7, 188:1-25.)

In 2010, Dr. Sorensen told Dr. Agomo and the office staff that Outreach Eyecare did not perform tonography and should not bill the measurement of eye pressure (IOP) as CPT Code 92120. According to Dr. Sorensen, he never personally checked off CPT Code 92120 on his billing sheets before or during his work with Outreach Eyecare. (Ex. R, 88:12-89:5; Ex. S, 114:4-115:18, 116:6-11, 135:17-23, 136:4-18, 138:4-140:3, 142:13-143:5; Ex. U, 179:19-180:1, 181:3-

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<sup>22</sup> Excerpts of Kimberly Latar Travis' deposition are attached as Exhibit "BB."

7, 196:7-201:22, 202:4-8, Ex. 16.) After conferring with Dr. Kibirige and reviewing documents presented by Dr. Sorensen, Dr. Agomo disagreed and informed Dr. Sorensen and the other optometrists that they could bill the measurement of eye pressure (IOP) with a Tono-Pen as CPT Code 92120. Dr. Kibirige told Dr. Agomo that CPT Code 92120 was a billable code based on the equipment they had in the office. (Ex. U, 171:13-175:22, 179:19-180:1, 181:3-183:23, 196:7-201:22, 202:4-8, Ex. 16.) Dr. Kibirige stated that the Tono-Pen met the definition of CPT Code 92120 because it was an indentation tonometer. (Ex. O, 229:14-231:23, 232:16-20, 246:12, 252:9-253:8, 254:15-255:4, 259:13-15.)

For service dates February 1, 2006, through December 31, 2011, Outreach Eyecare submitted 14,255 claims for CPT Code 92120 to the Medicare program and received \$794,783.07 from the Medicare program for these claims. For services dates February 1, 2006, through December 31, 2011, Outreach Diagnostic Clinic submitted 74 claims for CPT Code 92120 to the Medicare program and received \$4,070.70 from the Medicare program for these claims.<sup>23</sup> (Ex. CC, ¶¶ 3-9, Ex. 1.)

#### **IV. SUMMARY JUDGMENT STANDARD**

The Court should grant partial summary judgment to eliminate from trial those matters which are not subject to genuine dispute. Rule 56 states in part, “[t]he judgment sought shall be rendered forthwith if ... there is no genuine issue as to any material fact and ... the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). On a motion for summary judgment, where the record taken as a whole could not lead a rational trier of fact to find for the non-

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<sup>23</sup> Xiaoyang Sun’s affidavit is attached as Exhibit “CC;” a redacted copy will be filed with an unredacted copy filed under seal because the full contents are designated confidential with access restricted per court order of protection issued July 6, 2016.

moving party, there is “no genuine issue for trial” and the court must grant the motion.

*Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

The mere existence of some alleged factual dispute will not defeat a properly supported motion for summary judgment; the non-moving party must come forward with evidence sufficient for a jury to return a verdict in its favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251 (1986). Thus, if the non-movant’s allegations are merely colorable or are unsupported by evidence that is significantly probative, summary judgment may be granted. *Id.* The party opposing a motion under Rule 56 must present evidence in opposition and not merely show that there is some “metaphysical doubt” as to the material facts. *Matsushita*, 475 U.S. at 588. Even where portions of the matter appearing before the Court remain in dispute, summary judgment as to uncontroverted or previously established facts should be granted. Fed. R. Civ. P. 56(d).

Substantive law identifies which facts are material. Only disputes over facts that might affect the outcome of the suit will properly preclude the entry of summary judgment. *Id.* at 248. The standard for determining whether summary judgment should be granted “mirrors the standard for a directed verdict under Fed. R. Civ. P. 50(a), which is that the trial judge must direct a verdict if, under governing law, there can be but one reasonable conclusion as to the verdict.” *Id.* at 250. The question is not whether literally little evidence exists, i.e., a scintilla or less, but whether the nonmovant could, on the strength of the record evidence, carry the burden of persuasion with a reasonable jury. *Id.* at 252.

The United States in this matter satisfies the initial responsibility in moving for summary judgment. The United States informs the Court of the basis for the motion through the Statement of Facts and the attached exhibits, all of which demonstrate the absence of any genuine issue of

material fact, and demonstrate that the United States is entitled to judgment as a matter of law.

## V. ARGUMENT

### A. The False Claims Act

Enacted in 1863 in response to fraud during the Civil War, the FCA has been amended several times – most recently in 2009 – to bolster the United States’ ability to combat and deter false claims for payment from the Treasury. The statute was intended “to reach all types of fraud, without qualification, that might result in financial loss to the Government.” *United States v. Niefert-White*, 390 U.S. 228, 232 (1968). The Supreme Court has held that Congress wrote “expansively” to accomplish the statute’s remedial goal of protecting public funds from false and fraudulent claims. *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003).

A violation of the FCA occurs, *inter alia*, when any person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A).<sup>24</sup> Liability under this section of the FCA requires plaintiffs to demonstrate: “(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; and (3) with the knowledge that the claim was false.” *United States ex rel. Walker v. R & F Properties of Lake Cty., Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005).

“Knowing or knowingly” is defined in the FCA as: (1) having actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or

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<sup>24</sup> The FCA was amended by the Fraud Enforcement and Recovery Act of 2009, Pub.L. 111-21, May 20, 2009, 123 Stat.1617. The amendments apply to conduct on or after May 20, 2009, except that section 3729(a)(1)(B) is effective June 7, 2008; also, § 3731(b) is effective for all matters pending on May 20, 2009. The amendments did not affect former section 3729(a)(1), except to renumber it as section 3729(a)(1)(A). For convenience here, we use the FERA designation of the section.

(3) acting in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1).

Under the FCA, no proof of specific intent is required. *Id.* § 3729(b)(1)(B).

**B. Defendants' claims for reimbursement of tonography under CPT Code 92120 were false claims.**

A claim for services never provided is a false claim and unlawful. The Medicare program prohibits the submission of a claim for services never rendered. *See Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975); 42 U.S.C. §1320a-7. Under the FCA, a claim is factually false when the claimant misrepresents what goods or services that it provided to the Government. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir.2008).

The Defendants never performed tonography or the perilimbal suction method because they lacked the equipment to perform the services. Neither Dr. Kibirige nor Dr. Agomo ever performed tonography. Tonography is the measurement of facility of outflow (C) and requires an electronic Schiotz tonometer wired to a plotter and graphing paper. The electronic Schiotz tonometer indirectly measures facility of outflow (C) by continuously measuring and recording eye pressure readings over 4-5 minutes. The perilimbal method employs different technology to measure the facility of outflow (C). Dr. Kibirige and Dr. Agomo admitted that they nor the other Defendants ever performed tonography or the perilimbal suction method. At his deposition, Dr. Kibirige gave the following sworn testimony:

Q: While -- while Outreach Diagnostic Clinic was open, through the time that you owned it, did it ever perform any type of eye exams?

A: Outreach Diagnostic?

Q: Yes, Outreach Diagnostic Clinic.

A: No, sir.

Q: Any of the doctors that worked there at Outreach Diagnostic Clinic, did they perform any services for Outreach Eyecare?

A: No, sir.

Q: Did any of the doctors, including the optometrist from Outreach Eyecare, perform any services at Outreach Diagnostic Clinic?

A: No, sir.

Q: Any of the technicians that worked at Outreach Diagnostic Clinic, did they do any work for Outreach Eyecare?

A: No, sir.

Q: Any of the technicians from Outreach Eyecare perform any services out Outreach Diagnostic Clinic?

A: No, sir.<sup>25</sup>

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Q: Now, with regards to equipment for Outreach Diagnostic Clinic, did they have any equipment that was used for ophthalmological services?

A: No, sir.

Q: So there were no Tono-Pens at Outreach Diagnostic Clinic?

A: No, sir.

Q: They were no slit lamps at Outreach Diagnostic Clinic?

A: No, sir.

Q: And there were no Goldmann tonometers there?

A: No, sir.<sup>26</sup>

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A: Not only that, the tonography which you've been contesting, this is where also you are medically mistold, it is -- as -- Schiotz -- it has an instrument called a Schiotz, which I showed you when I first met you, with tonography.

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<sup>25</sup> Ex. O, 155:6-156:2.

<sup>26</sup> Ex. O, 167:2-13.

That equipment is gone. If somebody finds you in today's age in the clinic putting a tonograph on someone's eye, they will call the Medical Board on you, no question about it. As a matter of fact, somebody would shake their heads and say, "Where have you been? Where are you?"

It is not something to fly around and push around and show around, like Dr. Sorensen showing around. The technology was expired 30 years ago. It is equivalent, in my opinion, completely somebody -- remember where we used to open up people's brains, people who had seizures?<sup>27</sup>

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A: Yes, sir. And I didn't say tonography, because like the way I told you, if you saw somebody using the tonography, really, literally, somebody would be really -- I'm almost a hundred percent somebody jump off the table and say, "What the heck are you talking about?"

Q: So then what you're telling me today is that at no point from the time you started working with Dr. Hargrove (sic), although he did it, truth today, you yourself do not perform tonography?

A: No.

Q: And -- and in your Outreach Eyecare clinic, no one performed tonography?

A: No, sir. Mr. Vela, have you ever looked at that machine, or you just look it on the -- on the Internet? Have you ever looked at it at all?

Q: At the -- what -- what machine?

A: The tonography.

Q: I've looked at a machine that is claimed to be for tonography. I have not operated it.

A: Okay. It cannot be used in today's age, simple and clear. You can ask any ophthalmologist. Not with the current technology which we have.<sup>28</sup>

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Q: Other than the Tono-Pen, is there another medical device currently in use for eye pressure tests that would also fit that definition?

A: No, because the perilimbal suction method, that's also totally outdated. You can no longer really do that at all.<sup>29</sup>

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<sup>27</sup> Ex. O, 231:7-232:1.

<sup>28</sup> Ex. O, 250:2-252:1.

<sup>29</sup> Ex. O, 253:2-8.

Q: Then the last one, it says, "or perilimbal suction method." What does that mean to you?

A: It's really that technology also can no longer be applied.

Q: And that's not something that you did in your clinic?

A: No, sir.

Q: So Outreach Eyecare never performed that service?

A: No, sir.<sup>30</sup>

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Q: How do you spell Schiotz?

A: Schiotz is S-C-H-I-O-T-Z. What the Schiotz did, it was weight bearing on the eye, and give you a pressure recording. And what they did at that moment --I think 1950s -- they added on a tonographical recording on it, and they called it a tonography.<sup>31</sup>

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At his deposition, Dr. Agomo gave the following sworn testimony:

Q: All right. So the -- reading the -- the code, it says: (As Read) Tonography with interpretation and report, comma, recording indentation tonometer method or perilimbal suction method.

Starting with the first part of that, "tonography with interpretation and report," did the office perform tonography?

A: No.

Q: During the time that you've worked there, did they perform tonography on house calls?

A: No.

Q: And in the office?

A: No.<sup>32</sup>

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<sup>30</sup> Ex. O, 253:2-8.

<sup>31</sup> Ex. O, 254:5-14.

<sup>32</sup> Ex. U, 175:23-176:11.

Q: Perilimbal suction method, does the Tono-Pen meet that?

A: No.<sup>33</sup>

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Q: Did you ever perform tonography at medical school?

A: No.

Q: During your internship, did you perform tonography?

A: No.

Q: During your residency, did you perform tonography?

A: No.

Q: And as -- as a practicing doctor, have you ever performed tonography?

A: No.<sup>34</sup>

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Q: Do you know if Outreach Diagnostic Clinic performed any type of eye services?

A: You mean the Outreach diagnostic services?

Q: Correct.

A: To the best of my knowledge, no.

Q: So if, in fact, a patient were to present themselves at the diagnostic clinic and they needed some type of eye care or eye care services, would they be referred to the Outreach Eyecare clinic?

A: Correct.

Q: And is it your understanding that the doctors that worked at the Outreach Diagnostic Clinic, none of them were ophthalmologists?

A: No, they were not.

Q: And they did not have any optometrists?

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<sup>33</sup> Ex. U, 178:2-4.

<sup>34</sup> Ex. U, 178:18-179:4.

A: No.

Q: And is it your understanding that the doctors that did work at the Outreach Diagnostic Clinic, none of them performed eye care services?

A: They did not.<sup>35</sup>

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Based on its known technology, the Tono-Pen cannot measure directly or indirectly the facility of outflow (C) and therefore, cannot perform tonography. The patent and the manufacturer's manuals establish that the Tono-Pen only measures eye pressure (IOP) in mm Hg and does not measure anything else including the facility of outflow (C). Dr. Wallace's testimony as the Tono-Pen's inventor, Dr. Lee's testimony as a glaucoma specialist, the American Academy of Ophthalmology's *Basic and Clinical Science Courses*, and several medical textbooks support this fact. Medical residency programs through the United States offer the *Basic and Clinical Science Courses* to train ophthalmologists. Analogous to a portable electronic thermometer that measures a patient's present body temperature, the Tono-Pen is a portable electronic tonometer that measures in seconds the patient's present eye pressure (IOP). Neither device can continuously measure over a sustained period, 4-5 minutes, the patient's temperature or eye pressure respectively. They both provide a single measurement of the patient's body temperature or eye pressure (IOP) respectively. Dr. Kibirige and Dr. Agomo testified that they and the other Defendants measured glaucoma and glaucoma suspect patients' eye pressure (IOP) with the Tono-Pen. The Defendant's witness, Dr. Sabates agrees as well. At his deposition, Dr. Sabates gave the following sworn testimony:

Q. (BY MR. VELA) Right. So, I don't know either, but I'm asking you a question. In this document, does -- does the manufacturer ever refer to the term "tonography"? Does it use the word "tonography"?

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<sup>35</sup> Ex. U, 216:5-217:1.

A. It uses "tonometry."

Q. Does it state anywhere in here that it measures aqueous outflow?

A. No, it does not.

Q. So, it strictly measures intraocular pressure?

A. Correct.

Q. And does this device give you, as the person measuring intraocular pressure, does it give you the - - the information showing the - - the intraocular pressure continuously over time?

A. No, it does not.

Q. And approximately how - - how much time do you spend when you place the device on the eye?

A. A second, just rapidly, several times. I'd say three seconds, four seconds. The Tono-Pen is not made to measure aqueous outflow.<sup>36</sup>

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Q. And the Tono-Pen doesn't give you information about eye pressure over time, does it?

A. No.

Q. And it doesn't measure any phenomenon over time, does it?

A. No.

....

Q. (BY MR. RYTTING) If you use the Goldmann tonometer, can you bill?

A. No.

Q. And the Goldmann measures the exact same phenomenon as the Tono-Pen?

A. Yes.

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<sup>36</sup> Ex. DD, Vol. 1 209:12-210:8; Excerpts from Felix N. Sabates, Jr., M.D. deposition volume 1 are attached as Exhibit "DD."

Q. And it gives you the same amount of information as the Tono-Pen?

A. It gives you pressure, correct.<sup>37</sup>

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Q. Now, on the Tono-Pen's screen, what will appear is a single number, correct?

A. Correct.

Q. And the unit of measurement is millimeters per mercury, correct?

A. Of course, yes. Of mercury - - millimeter of mercury.

Q. Millimeters of mercury?

A. Correct.

Q. Now, there is no - - there is no measurement of reading or display of time, is there?

A. No.

Q. And other than a single number, there is no display - - in other words, there's no display of more than one number, is there?

A. No.

Q. And if, in fact, there was a change in intraocular pressure for any duration, that change is not reflected on that screen, is it, the difference?

A. No.

Q. And the Tono-Pen is -- it's incapable of producing a written graph that would - - that would be able to mark on the graph every single measurement of pressure per time?

A. No. You're correct.

Q. And when you mentioned earlier that these 500 notes per second, is there "any way to verify within the Tono-Pen if, in fact, 500 notes per second are being measured or if it can be less or if it can be more?

A. No.

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<sup>37</sup> Ex. DD, Vol. 1 301:15-302:8.

Q. And it's also true and you testified to this yesterday that the Tono-Pen does not measure the aqueous humor outflow?

A. Correct.<sup>38</sup>

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Q. And you already testified that the Tono-Pen does not provide you changes. It provides you a single reading, correct?

A. Correct.

Q. All right. And I'm going to drop down to the next definition of tonography Farlex Partner Medical Dictionary. It states there "Continuous measurements of intraocular pressure by means of a recording tonometer to determine the facility of aqueous outflow." Now, you've already testified yesterday and today the Tono-Pen does not determine the facility of aqueous outflow, correct?

A. Correct.<sup>39</sup>

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Q. (BY MR. VELA) On the screen of the Tono-Pen, the unit of measurement is millimeters of mercury?

A. Of course. Yes.

Q. But there's no measurement per second, per minute, per hour, per day, per week, none of that?

A. No.<sup>40</sup>

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In light of the undisputed facts, Outreach Eyecare's 14,255 claims and Outreach Diagnostic Clinic's 74 claims submitted or cause to be submitted by the Defendants to the Medicare program for tonography, CPT Code 92120, were factually false and constitute false claims under the FCA.

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<sup>38</sup> Ex. EE, Vol. 2 94:21-96:3; Excerpts from Felix N. Sabates, Jr., M.D.'s deposition volume 2 are attached as Exhibit "EE."

<sup>39</sup> Ex. EE, Vol. 2 102:7-19.

<sup>40</sup> Ex. EE, Vol. 2 104:19-24.

**C. Defendants *presented or caused to be presented* the false claims for reimbursement of tonography under CPT Code 92120.**

A person or entity that implements or adopts a policy that results in another person or entity in submitting false claims is liable for causing the submission of false claims. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004); *United States v. Caremark, Inc.*, 634 F.3d 808 (5th Cir. 2011); *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F.Supp. 2d 654, 666 (S.D. Tex. 2013). At Physician Eye Associates, Dr. Kibirige and Dr. Mapp developed, approved, and implemented a billing sheet that documented the services they billed to third party payors like Medicare.<sup>41</sup> Until K & S Consulting revised the billing sheet in 2006, Outreach Eyecare continued to use the same billing sheet to document the clinic's services. The original and the revised billing sheets included a procedure "Pressure Check" with CPT Code 92120 that the clinic's ophthalmologists, optometrists, and technicians knew to check off when measuring a glaucoma or glaucoma suspect's eye pressure (IOP) with a Tono-Pen. Dr. Kibirige personally reviewed, approved, and authorized the original and revised versions of the billing sheet that included the procedure "Pressure Check" with CPT Code 92120. Dr. Kibirige adopted and implemented the policy to bill the measurement of eye pressure (IOP) with a Tono-Pen under CPT Code 92120. At his deposition, Dr. Kibirige gave the following sworn testimony:

Q. So can we agree that during the time that --that Medicare paid for 92120, it remained on the superbill?

A. Yes, sir.

Q. And whenever a pressure check was performed either in a house call or in the office, it would be -- it would be checked off on this form and billed under 92120, correct?

A. Yes, with the Tono-Pen.

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<sup>41</sup> Ex. O, 46:15-50:25, 61:20-62:23.

Q. With the Tono-Pen and the house call?

A. Yes.

Q. And in the office, with the Goldmann tonometer?

A. No, with the Tono-Pen. As long as it's done by the Tono-Pen, that's -- the code was billed because of the Tono-Pen.<sup>42</sup>

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Q. So 92120, for your clinic, was reserved only for when the Tono-Pen was used?

A. Yes, sir.

Q. And -- and if they did have the Goldman tonometer, there would be no need to also use a Tono-Pen at the same time?

A. Absolutely not.

Q. And what you're telling me is the -- that when the clinic started billing for 92120, in actuality, when you first started working here in Houston with the other doctor, the Physician Eye Associates, they were billing 92120?

A. Dr. Hargrove Wooten -- so that you could really understand this -- for him, it was old-fashioned technology. He was an old guy who was 70 years of age. Believe it or not, for him, he still had the tonography.

Q. Was he using the tonography?

A. We had to tell him to stop it.

Q. And at that point, did you switch to the Tono-Pen?

A. Yeah.

Q. So when he was using the old technology -- Yeah.  
-- the tonography, he was, in fact, billing 92120 --

A. He --

Q. -- for that technology?

A. Yes, he was.

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<sup>42</sup> Ex. O, 226:24-227:13.

Q. And then when you switched over to the Tono-Pen, you continued to use 92120, but now for the Tono-Pen?

A. It was for the Tono-Pen. . . .<sup>43</sup>

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Q. But is -- what you testified today, it was perfectly legitimate and appropriate and expected that 92120 would be submitted for eye pressure tests, correct?

A. Yes.

Q. And that was known to the staff, correct?

A. Was known, you mean, to the -- to the doctors?

Q. The doctors, the technicians, the office manager; they all knew this, correct?

A. What do you mean, Mr. Vela, they all knew that 92120 is to be circled or -- it depended completely on what the doctor has done and his work of circling of his job.

Q. That for eye pressure tests that are on the superbill --

A. Yes.

Q. -- the procedure code next to it is 92120, correct?

A. Yes.

Q. There is no other procedure code that's next to that procedure, correct?

A. No.

Q. So if that procedure is performed, be it in the office or on a house call, 92120 is the code to circle?

A. To circle with a Tono-Pen. And I think we went through that, you and me.

Q. Right. But we're talking about a pressure test with 92120 next to it on that form, correct?

A. Now you are confusing me.

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<sup>43</sup> Ex. O, 247:7-248:14.

Q. On the superbill under the procedures, it shows, "Pressure check CPT Code 92120"?

A. For the patients who have glaucoma or glaucoma suspect, after they have come in and follow up appropriately for pressure check, yes, it was marked.

Q. And that was known because it was on the superbill?

A. By the doctors, yes, if they performed those services.

Q. The doctors were not the only ones that handled those superbills, correct?

A. No.

Q. Miss –

A. The doctor, the people who -- and the billing company. That's my understanding.

Q. The billing –

A. Yes.

Q. The billing company, yes?

A. Yes.

Q. Ms. Williams, yes?

A. Yes.

Q. And also your checkout staff, yes?

A. Yes.<sup>44</sup>

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After receiving Dr. Sorensen's email and discussing with Dr. Kibirige the use of CPT Code 92120 for the measurement of eye pressure (IOP) with a Tono-Pen, Dr. Agomo encouraged and maintained Dr. Kibirige's policy to bill this measurement under CPT Code 92120. He

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<sup>44</sup> Ex. O, 344:12-346:17.

advised Outreach Eyecare's doctors that billing the measurement of eye pressure (IOP) under CPT Code 92120 was appropriate. Dr. Agomo gave the following sworn testimony:

Q. Right. But wasn't it Dr. Sorensen's position that 92120 was not an appropriate code for Tono-Pens?

A. That was his -- that was his position.

Q. Right. And you don't agree with that position?

A. I don't.

Q. And now, did you respond to that e-mail?

A. Yes, I -- I responded to the e-mail in our meeting with the doctors where I clearly went over the functioning of the Tono-Pen.

Q. So you explained it?

A. Correct.

Q. And you also informed them that the use of 92120 was appropriate?

A. Correct.

Q. Did the other doctors agree with you?

A. Well, there was -- there was no -- no real consensus. Some did, some don't, some were on the fence.

Q. Who were the doctors that outright did not agree with you?

A. Dr. Sorensen.

Q. Any other doctors did not agree with you?

A. To the best of my knowledge, no.<sup>45</sup>

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As discussed previously, Outreach Eyecare's billing staff took the completed billing sheets from the clinic's doctors, and if complete, sent the billing sheets' information including

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<sup>45</sup> Ex. U, 182:8-183:6.

the procedure code for the services rendered to the third party billing company either K & S Consulting or GHA. For their part, the third party billing companies received the information from Outreach Eyecare or Outreach Diagnostic Clinic, and if complete, submitted the claims on behalf of Outreach Eyecare or Outreach Diagnostic Clinic to third party payors like Medicare. Because of Defendants' policy to bill measurements of eye pressure (IOP) with the Tono-Pen under CPT Code 92120, they caused K & S Consulting or GHA to submit 14,255 false claims for Outreach Eyecare and 74 false claims for Outreach Diagnostic Clinic to the Medicare program in violation of the FCA.

**D. Defendants *knowingly* presented or caused to be presented false claims for reimbursement of tonography under CPT Code 92120.**

A person or entity who adopts a patently unreasonable interpretation of a rule, regulation, or standard acts with deliberate ignorance and possess the requisite knowledge in submitting false claims in violation of the FCA. *See Commercial Contractors, Inc. v. United States*, 154 F.3d 1357 (Fed. Cir. 1998). Likewise, a person or entity who receives, but ignores, information that should have put them on notice that their claims were improper acts with requisite intent under the FCA. *See United States v. Lorenzo*, 768 F. Supp. 1127 (E.D. Pa. 1991). Dr. Kibirige justified Outreach Eyecare's billing the measurement of eye pressure (IOP) with a Tono-Pen under CPT Code 92120 primarily on two items: a seminar sponsored by a pharmaceutical company and his own interpretation of the CPT Code 92120. Dr. Kibirige did not produce any evidence to support his assertions that the pharmaceutical company advised him to bill this way. Dr. Kibirige gave the following sworn testimony:

Q. And then when you switched over to the Tono-Pen, you continued to use 92120, but now for the Tono-Pen?

A. It was for the Tono-Pen. For him, like again -- again, you know, I had a glaucoma specialist in the clinic, which was Dr. Mapp.

There was no need for me to really do -- all the glaucoma patient and glaucoma suspects were followed by Dr. Michael Mapp until when we separated. Then I inherited all those patients.

Then we went to billing courses, and they told us that, "Oh, by the way, for you guys who are not in glaucoma subspecialties, you are forgetting to use this code."

I remember really, really well, I went to the course with Allergan and they completely pointed it out. It was actually on the the Power slide, and then we all completely said, "Oh, why not?"

And that -- that training that you received from -- how do you spell the company, Allergan? Allergan is a company which you use which sells glaucoma eye drops. And what they do, routinely companies which sell glaucoma eye drops, they bring in CME credit courses with a external speaker, a professor from Baylor.

And the billing coding, they may bring just a coding company independently, or they may bring a professor independently to teach you about something, either coding or billing of glaucoma.

Q. And that particular training that you received, that would have been early when you started Outreach Eyecare?

A. Yes, sir.

Q. And as a result of that exposure, you were informed that 92120 could be used for pressure checks?

A. Yes, sir.<sup>46</sup>

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Dr. Kibirige's second and main justification is his personal interpretation of CPT Code 92120. As written, CPT Code 92120 states:

**92120** Tonography with interpretation and report, recording indentation tonometer method or perilimbal suction method

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<sup>46</sup> Ex. O, 248:11-249:25.

Dr. Kibirige interpreted CPT Code 92120 as covering three separate items: (1) tonography, (2) recording indentation tonometer method, and (3) perilimbal suction method. He readily admitted that he nor his clinics performed tonography or the perilimbal suction method. He further interprets *recording indentation tonometer method* as a reference to the Tono-Pen because he believes that the Tono-Pen is an indentation tonometer that fits this description. He views the code as an equipment code for the use of the Tono-Pen. Dr. Kibirige gave the following sworn testimony:

Q. Now, the use of the Tono-Pen for the pressure check, what is it about the Tono-Pen that would qualify it to be billed under 92120?

A. Thank you for asking. Really that question should have been asked a long time ago, Mr. Vela. A Tono-Pen, they contest the code which -- and are contested by the government. The 92120 specifically says indentation, indentation telemetry, and the Tono-Pen, that's exactly what is defining it.

Q. And --

...

A. And -- and I don't know where we missed the boat. I don't know where Dr. Sorensen miss --missed the boat. And on yourself, actually, honestly, I will be outright honest -- honest with you, you are completely misinformed.

A Tono-Pen has, in any textbook on a higher level -- not the Internet, take a picture out and say, "This is a Tono-Pen" -- it totally is defined as a applanation with indentation.<sup>47</sup>

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A. And I'm stopped. I mean, a code like this, 92120, No. 1, there is lack of adequate knowledge on glaucoma suspect. Really, there is. You're not in the medical field. I'm not going to blame you on that.

But he knows a little better than that. He knows that he had a -- a fallout with Dr. Agomo and he's limited with the scope of knowledge.

There are books on glaucoma sus- --I'm not making these things up. There -- on the Tono-Pen, it all boils up on the Tono-Pen versus the tonography.

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<sup>47</sup> Ex. O, 229:14-230:17.

You're going to get those actual codes, you're going to read them, and you're going to say, Oh my goodness. What the heck? It's going to completely change who you are. The code defines a Tono-Pen.<sup>48</sup>

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Q. Then, comma, "recording indentation tonometer method," what does that mean to you?

A. That is what -- exactly what the Tono-Pen says.

Q. So -- so your understanding is that the Tono-Pen would qualify as a recording indentation tonometer method?

A. Absolutely.<sup>49</sup>

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Fatally flawed, Dr. Kibirige's interpretation is implausible and unreasonable because the plain meaning of the CPT Code 92120 does not support his interpretation. Grammatically, CPT Code 92120 reads as follows - Procedure X, method "A" or method "B." CPT Code 92120 gives you the name of Procedure X, *Tonography*, followed by a comma ",". After the comma, CPT Code 92120 provides two methods to perform *Tonography*, method "A", *recording indentation tonometer method*, followed by "or" followed by method "B", *perilimbal suction method*. As written, CPT Code 92120 does not present three separate items in a series. That would have at least required a comma "," after *recording indentation tonometer method*. Merriam-Webster's Dictionary defines "method" as "a way, technique, or process of or for doing something." In the case of CPT Code 92120, the *recording indentation tonometer method* must be read to mean a technique to perform the procedure tonography. Therefore, the *recording indentation tonometer method* must be a technique to measure the facility of outflow (C). *Tonography* and the *perilimbal suction cup method* are both techniques to measure the facility of outflow (C). The electronic Schiotz tonometer is an indentation tonometer that indirectly

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<sup>48</sup> Ex. O, 245:19-246:12.

<sup>49</sup> Ex. O, 252:20-253:1.

measures the facility of outflow and squarely fits the term *recording indentation tonometer method*. The Tono-Pen does not directly or indirectly measure the facility of outflow and therefore cannot fit the term *recording indentation tonometer method*.

Undeterred by these facts, Dr. Kibirige sets out in this case to defend his interpretation with some articles, a complimentary procedural coding booklet, and the testimony of Dr. Sabates. Dr. Kibirige states that the Tono-Pen is an indentation tonometer and therefore, a *recording indentation tonometer*. In support, he presents some articles that label the Tono-Pen as an indentation tonometer as opposed to an applanation tonometer like the Goldmann tonometer. He presents a coding booklet, *Ophthalmology Expert a procedural coding companion*, published by Ingenix that explained CPT Code 92120. He presents Dr. Sabates' testimony in support of his defense. There are several problems with Dr. Kibirige's defense.

First, none of the articles state that the Tono-Pen can perform tonography or measure facility of outflow (C). The American Medical Association, the publishers of the *Current Procedural Terminology* (CPT Code manual), nor CMS or its Medicare contractors reviewed, approved, published, or warranted the explanation of CPT Code 92120 contained in the coding booklet *Ophthalmology Expert a procedural coding companion*. The booklet's explanation did not identify the Tono-Pen as equipment that performs tonography or measures facility of outflow (C). Ingenix published this booklet in 2009, several years after Dr. Kibirige and his clinics started billing CPT Code 92120. This booklet would not have informed the Defendants prior to implementing their policy to bill the measurement of eye pressure (IOP) under CPT Code 92120.

Second, Tono-Pen's patent, inventor, and product manuals, along with standard medical textbooks and the American Academy of Ophthalmology's *Basic and Clinical Science Course*

establish that the Tono-Pen is an applanation tonometer. Although Dr. Sabates testified that the Tono-Pen was an indentation tonometer in contradiction to well established science, he acknowledged that the Tono-Pen could not measure eye pressure continuously over 4-5 minutes nor could it measure facility of outflow (C). In fact, Dr. Sabates admitted that neither he nor his father or brother, both recognized ophthalmologists, ever billed the measurement of eye pressure (IOP) with a Tono-Pen under CPT Code 92120. Dr. Sabates gave the following sworn testimony:

Q. (BY MR. VELA) Did you ever bill for the use of a Tono-Pen under 92120?

A. No.

Q. So, between the time that you started practicing medicine and though today, have you ever billed under Procedure Code 92120?

A. No.<sup>50</sup>

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Q. Now is it fair to say that you, your father, and your brother all use the same technique for measuring eye pressure with the Tono-Pen?

A. Yes.

Q. Now, do you know whether or not your father has ever billed the use of the Tono-Pen under CPT Code 92120?

A. He has not.

Q. And what about your brother?

A. He has not.<sup>51</sup>

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Q. (BY MR. VELA) And - - and, again, you - - in your time working as a doctor, you have treated patients with glaucoma?

A. Yes.

Q. And you have used the Tono-Pen to measure eye pressure on these patients?

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<sup>50</sup> Ex. DD, 163:1-7.

<sup>51</sup> Ex. DD, 244:21-245:5.

A. Yes.

Q. But you have never billed those services under 92120?

A. No.

Q. And to your knowledge, your father never has?

A. No.

Q. And to your knowledge, your brother never has?

A. No.<sup>52</sup>

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Q. And in your time as a practicing physician in regards of seeing glaucoma patients in regards of you using the Tono-Pen, you have never billed Medicare or any private insurance company for that matter procedure code 92120?

A. No.

Q. And, to your knowledge, nor has your brother. Dr. Nelson?

A. To my knowledge.

Q. And, to your knowledge, nor that is your father, Dr. Felix Sabates, Sr.?

A. To my knowledge, no.<sup>53</sup>

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Finally and most important, whether the Tono-Pen is an indentation tonometer or an applanation tonometer is immaterial to this case. Simply, the Tono-Pen like the Goldmann tonometer and the standard Schiotz tonometer only measures eye pressure (IOP) in mm Hg at a single point in time. Unlike the electronic Schiotz tonometer, the Tono-Pen cannot measure eye pressure (IOP) continuously over 4-5 minutes and cannot indirectly or directly measure facility of outflow (C). The Tono-Pen is a portable tool that measures eye pressure like a portable electronic thermometer that measures body temperature at a single point in time.

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<sup>52</sup> Ex. DD, 291:10-20.

<sup>53</sup> Ex. EE, 126:1-12.

In light of the Tono-Pen's technology and the grammatical structure of CPT Code 92120, Dr. Kibirige's interpretation is implausible and wholly unreasonable.

For his part, Dr. Agomo merely parroted Dr. Kibirige's interpretation. Dr. Agomo did not look beyond Dr. Kibirige's interpretation or his own reading of CPT Code 92120. He too concluded that the Tono-Pen was an indentation tonometer that met the description of *recording indentation tonometer method*. He ignored Dr. Sorensen and the documents he presented to Dr. Agomo by not seeking additional guidance beyond Dr. Kibirige. Dr. Agomo gave the following sworn testimony:

Q. Okay. So what you're telling me is, other than what you read on the CPT manual itself, you did not -- you did not look at any other reference material, correct?

A. There was no need -- this is pretty self-explanatory, in my mind.

Q. And you didn't consult with anyone outside of Outreach Eyecare about 92120, correct?

A. I asked -- outside of 9 -- outside of Outreach?

Q. Yes, outside of Outreach Eyecare.

A. I talked -- I discussed with my senior colleague, Dr. K.

Q. Dr. who?

A. Dr. Kibirige.

Q. And did you discuss it with him when you started in 2010?

A. Yes.

Q. And did you bring up the topic, or did he bring up the topic?

A. No, it's -- it's -- it was -- it was probably -- I don't -- I don't recall, but it was just, "It is a billable code based on the equipmentation" -- "equipment we have in the office."

Q. And was -- were you advising him, or was he advising you?

A. It was something, more or less, he was telling me.<sup>54</sup>

Based on Dr. Kibirige and Dr. Agomo's guidance, Outreach Eyecare's staff filled out billing sheets with CPT Code 92120 for measurements of eye pressure (IOP) with a Tono-Pen and sent this information to their billing companies who submitted these false claims to the Medicare program for reimbursement. There is no evidence that the Defendants sought or obtained guidance regarding CPT Code 92120 from the American Medical Association, the publishers of CPT Code 92120. Likewise, there is no evidence that the Defendants sought or obtained guidance regarding CPT Code 92120 from CMS or its Medicare contractors, the administrators of the Medicare program. Under the FCA, Dr. Kibirige, Dr. Agomo, Outreach Eyecare, and Outreach Diagnostic Clinic acted with "deliberate ignorance" by adopting a purported interpretation of CPT Code 92120 that bordered on the frivolous, was implausible, and unsupported by the Tono-Pen's technology or the plain meaning of CPT Code 92120. In fact, CPT Code 92120 existed before the United States Patent and Trademark Office issued a patent for the Tono-Pen on May 31, 1988.<sup>55</sup> The Defendants acted with the requisite intent in violation of the FCA.

## **VI. DAMAGES AND CIVIL PENALTIES**

Any person who violates the FCA is liable to the United States Government for a civil penalty of not less than \$5,500 and not more than \$11,000 and 3 times the amount of damages, which the Government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1); *See*

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<sup>54</sup> Ex. U, 172:23-173:25.

<sup>55</sup> Ex. N, pp. 1-14; Ex. FF, pp. 1-19; Excerpts from the American Medical Association's Current Procedural Terminology (CPT) Manual from years 1987, 1992, 1998, 2000, and 2002 are attached as Exhibit "FF."

Civil Monetary Penalties Inflation Adjustment, 64 Fed. Reg. 47,099-01, 47,103-47,104 (Aug. 30, 1999). In this case, each Defendant presented or caused to be presented false claims to the United States. As detailed in Exhibit “CC,” the United States’ Medicare program received 14,255 claims for CPT Code 92120 and paid \$794,783.07 to Outreach Eyecare. Further, the United States’ Medicare program received another 74 claims for CPT Code 92120 and paid \$4,070.70 to Outreach Diagnostic Clinic. Based on the undisputed facts, the United States suffered damages of \$798,853.77 ( $\$794,783.07 + \$4,070.70$ ).

Each Defendant is liable to the United States for each false claim and for the total amount of the damages suffered by the United States. The United States paid for services never rendered. The Defendants never performed tonography for which they fraudulently billed or caused third party billing companies to bill the Medicare program more than 14,300 times and as a result received \$798,853.77 that they were not entitled to receive. At the same time, the Defendants billed or caused third party billing companies to bill Medicare more than 21,000 times and received \$1,718,113.01 for office and house call visits that included payment for the measurement of eye pressure (IOP) with the Tono-Pen or Goldmann tonometer. These billing and payment details are provided in Exhibit “CC.” This was not a case of up-coding, but a case of services not rendered. The government paid the Defendants for the measurement of eye pressure (IOP) with the Tono-Pen as an integral part of the office or house call visit. Therefore, the United States is entitled to the return of the full amount paid for CPT Code 92120 claims. Under the FCA, each Defendant is liable to the United States for treble damages of \$2,396,561.31 ( $\$798,853.77 \times 3$ ).

The FCA's civil penalties provision are considered punitive in nature subject to Eighth Amendment excessiveness analysis. *See Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000); *United States ex rel. Chandler v. Cook County, Ill.*, 277 F.3d 969, 977 (7th Cir. 2002). The FCA's civil penalties violates the Excessive Fines Clause if it is "grossly" disproportional to the gravity of the defendant's offense. *See United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 387 (4th Cir. 2015). Courts evaluate whether the government's recovery is excessive in light of the extent and harm resulting from the defendant's conduct. *See United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp 2d 719, 745 (N.D. Ill. 2007); *United States v. Mackby*, 221 F. Supp. 2d 1106, 1111 (N.D. Cal. 2002).

In this case, Defendants devised a scheme to defraud the government by billing for services impossible to perform. The Defendants admitted they lacked the equipment, knowledge, or experience to perform tonography. Yet, the Defendants submitted 14,329 claims under CPT Code 92120 to receive payment for measuring eye pressure (IOP) with a portable tonometer, Tono-Pen. The Defendants knew that the Tono-Pen could only measure eye pressure (IOP) at a single point in time and could not measure facility of outflow (C) as required by CPT Code 92120. When confronted by Dr. Sorensen and this lawsuit, the Defendants presented an unreasonable interpretation of CPT Code 92120 that was patently false and completely without merit. There is simply no evidence to support their interpretation.

The Defendants' actions reflect a serious, ongoing, and deliberate course of conduct designed to obtain Medicare payments for which they were not entitled to receive. Fraudulent claims make the administration of Medicare more difficult, and widespread fraud would

undermine public confidence in the system. *See United States v. Macby*, 339 F.3d 1013, 1019 (9th Cir. 2003). Based on their conduct and the harm caused to the Medicare program, each Defendant should be liable to the United States for civil penalties of \$1,597,707.54 (\$798,853.77 x 2). The Defendants' fraudulent conduct was pervasive with more than 14,300 false claims spread over six years. They only stopped because the Medicare program stopped paying for CPT Code 92120 on January 1, 2012. They billed until December 31, 2011. The proposed civil penalties are not excessive under the Eight Amendment of the United States Constitution.

## **VII. CONCLUSION**

Each Defendant violated the FCA through a scheme to bill under CPT Code 92120 the Medicare program for single eye pressure (IOP) measurements taken with a Tono-Pen. Medicare already covers these measurements under CPT procedure codes 92002, 92004, 92012, 92014, 99344, 99348, 99349 as part of office or home visits. The Tono-Pen cannot measure facility of outflow (C) and therefore cannot perform tonography under CPT Code 92120. The Defendants' interpretation of CPT Code 92120 is absurd and implausible given the plain meaning of the procedure code and the science behind the Tono-Pen. There is no material issue of fact related to the conduct of the Defendants, the science behind the Tono-Pen, or the plain meaning of CPT Code 92120. As a result, each Defendant is liable to the United States for treble damages of \$2,396,561.31 and civil penalties of \$1,597,707.54. The United States is entitled to summary judgment against Dr. Kibirige, Dr. Agomo, Mustapha Kibrige, M.D., P.A. d/b/a Outreach Eyecare, and Outreach Diagnostic Clinic, LLP, jointly and severally, in the minimum amount of \$3,994,268.85.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the *United States Motion for Partial Summary*

*Judgment* has been sent by via ECF by the Clerk or regular mail on March 8, 2019, to:

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